UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION,	Lead Case No.: 3:21-cv-03825-VC
THIS DOCUMENT RELATES TO: ALL CASES	
SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff, vs. INTUITIVE SURGICAL, INC., Defendant.	Case No. 3:21-cv-03496-VC

HIGHLY CONFIDENTIAL - ATTORNEYS EYES ONLY

REMOTE PROCEEDINGS OF THE VIDEOTAPED DEPOSITION OF
INTUTITIVE SURGICAL, INC.,
BY AND THROUGH ITS 30(B)(6) DESIGNEE,
GRANT DUQUE
TUESDAY, NOVEMBER 8, 2022

REPORTED BY NANCY J. MARTIN
CSR. NO. 9504, RMR, RPR
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Tuesday, November 8, 2022

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Videotaped Remote Deposition of INTUTITIVE SURGICAL, INC., by and through its 30(B)(6) designee GRANT DUQUE, beginning at 3:15 p.m., before Nancy J. Martin, a Registered Merit Reporter, Certified Shorthand Reporter. All parties appeared remotely.

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BEN PELTA-HELLER, LEGAL VIDEOGRAPHER

Page 50 and maybe table 3.3 and let me know when you're ready to discuss that.

A. Okay. Page 50?

Q. I'm sorry. Why don't we go to -- I misled you. Could we go to Page 49? The bottom of that page provides some useful context. If you start there and read onto Page 50, I think that will make sense.

A. Okay.

(The witness reviewed the document.)

THE WITNESS: Okay. I did read that.

BY MR. VAN HOVEN:

Q. Yes. Do you have a general understanding of what tables 3-3 through 3-10 are supposed to represent in the context of this document? And maybe just -- let's just refer to it in the context of 3-3 and then we can go to any others if we want.

A. I'm familiar with them and am familiar with what's being discussed, yes.

Q. And do these appear to be summaries of previously done reliability testing for XI instruments and in this case, for 3-3, Maryland Bipolar Forceps?

A. I apologize. Can you repeat your question?

Q. Sure. Maybe I'll kind of set it up a little bit. There's a -- this document is referring to predicate devices to the EUP devices?

A. That's right.

Q. And the predicate devices are the originally cleared devices that the EUP devices are based on?

A. That's correct.

Q. Are these tables referring to test results for the predicate devices?

A. Yes, that's correct.

Q. And, for example, we talked a little bit about simulated uses earlier today. It appears that, if we look at the bottom of Page 50, there's some discussion of simulated surgical use in the context of an 8 mm Maryland Bipolar Forceps?

A. Yes, I see that.

Q. There's a table on the next page. And do you have an understanding of what this table is representing?

A. I'm reading it now, and this is a summary of the results of that predicate instrument testing.

Q. The predicate instrument life testing?

A. That's right.

Q. There's a column. Hopefully it's a little better on your printed document, but it looks like it's Performance Requirement/Acceptance Criteria, the second column?

A. I do see that, yes.

Q. I guess that's a high-level listing of the criteria that were tested during the life test?

A. That's accurate, yes.

Q. And then there's -- under that, it says, "A Weibull Design of Reliability analysis with a 90/90 reliability and confidence"?

A. I see that, yes.

Q. That would conform to a C2-type criteria; is that right?

A. That's correct.

Q. And it notes that that resulted in 10 human uses as the -- or that's what it says there?

A. That's correct.

Q. Do you have an understanding of what that means in the context of the performance requirement acceptance criteria?

A. I have an understanding of what that means, yes.

Q. What's that?

A. That these predicate devices, the Maryland Bipolar Forceps, that are titled here went through the life testing and satisfied the performance requirements and acceptance criteria to satisfy a 90/90 confidence reliability calculation for 10 lives, 10 human uses.

Q. And there's a conclusion on the rightmost column.

A. I see that.

Q. It notes that, "All tests articles completed 13 life cycles"?

A. That's right.

Q. And then it states that, "Since the performance of the instruments was subsequently determined to be acceptable through life testing and achieve 13 life cycles, the resulting number of human uses is 10."

A. I see that.

Q. Do you have an understanding of what that's referring to?

A. I do.

Q. What's that?

A. For the Weibull calculation, depending on the sample size or number of samples that survived the extent of the test, to substantiate or to qualify for a 90/90 confidence and reliability, you may have to test some of the devices beyond 10.

So what I'm seeing here, all of the test articles completed 13 life cycles, but that was in order to satisfy the 90/90 confidence and reliability for a 10-life instrument.

Q. What does completed 13 life cycles mean?

A. The life cycles, those are SSUs. So those are the simulated surgical uses on a system. That's what that's referring to.

Q. And in this example, all the test samples would have made it through 13 simulated surgical uses without failure?

A. According to the statement, yes.

Q. And would that be examples of samples that are censored?

MS. CAHOY: Objection to form.

THE WITNESS: For the Weibull calculation, if they are surviving, they would be censored as they would be censored at the number of use cycles that they completed, yes.

BY MR. VAN HOVEN:

Q. I'd like to go to the table 3-4. If you could take a look at the description, the summary, and the table itself and let me know when you're ready to discuss those.

A. I see it. I'm ready.

Q. And here there are some -- in the second column, do you see there's a Test Category?

A. I do.

Q. And one category is Damage Requirements?

C1-type failure?

A. That's correct.

Q. I'd like to go to page -- I think it's starting on Page 54. That's table 3-6. If you'd take a look at the discussion on Page 54 and the corresponding table on Page 55.

(The witness reviewed the document.)

THE WITNESS: Okay. I've read it, yes.

BY MR. VAN HOVEN:

Q. Does this appear to be a life-testing summary for the Large Needle Driver?

A. It does.

Q. I guess the original sub- -- the originally designed Large Needle Driver; is that right?

A. The 10-life, yes.

Q. And I'd like to go to the table on Page 55. The conclusion states that, "All test articles completed 15 cycles."

Do you see that?

A. I do.

Q. Does that mean that all the test articles used for the Large Needle Driver life testing completed 15 surgical uses without failure?

A. That looks accurate.

Q. And would those results have been censored

for the purpose of Weibull analysis?

A. Yes, they would.

Q. At their 15 completed surgical uses?

A. That's correct.

Q. I'd like to take a look at the Mega SutureCut Needle Driver on Page 55 through 56.

A. Okay.

Q. And let me know when you're ready to discuss that.

A. I'm ready. These are very similar.

Q. And so for the Mega -- I guess for the originally designed Mega SutureCut Needle Driver, did all test articles complete 15 cycles without failure?

A. That looks correct per the conclusion statement.

Q. And all of those test articles then would have been censored for the purpose of Weibull analysis?

A. You have me thinking about that question because -- and if we are calculating -- if there was a need to calculate Weibull -- so this -- and this applies to my previous answer to that. We would have had to censor those four samples at the 15 lives.

But I'm looking at the write-up here, and I'm seeing that the sample size is clearly identified

here. For the Mega SutureCut Needle Drivers, it looks like there's a sample size of four.

So that -- if they knew the protocol -- if they knew the sample size at the beginning of execution of the protocol, they would know what number of lives without failure the four test units would have to survive to prove the 90/90. So it would have been a target.

Q. In this case, the target of 10 uses?

A. Correct. Correct.

And so after they meet that target, there wouldn't necessarily be a need to do an explicit Weibull calculation. They would have achieved what the protocol pass/fail criteria was.

Q. Got it. Essentially in that case because there were no failures; right?

A. Right. And they met the protocol pass/fail criteria, assuming that there were four test units.

Q. Got it. I'd like to go to table 3-10 on Page 59. This is discussing the original XI design for 8 mm ProGrasp Forceps and 8 mm Long Tip Forceps; is that right?

A. I see that under the bold header.

Q. Could you take a look at the write-up and the table on the following page.

A. Yeah. I'm noticing that it doesn't say ProGrasp and Long Tip. It says "ProGrasp Forceps and Tenaculum Forceps." So that looks inconsistent.

Q. So you're saying the types of forceps identified in the conclusion in the right side column are possibly inconsistent with the ones on the title on the previous page; is that right?

A. That's what I'm observing, yes.

Q. So I'll focus on what's in the -- what's in the table.

A. Okay.

Q. First in the conclusion, there's one set of test results for the original XI design of the ProGrasp Forceps.

Do you see that?

A. I do see that.

Q. There it says that, "All test articles completed their 13 life cycles"?

A. I see that, yes.

Q. Do you understand that to be an instance in which all of the test articles made it to 13 life cycles without failure?

A. I do.

Q. And Tenaculum Forceps. Am I saying that right?

A. Yes, that's right.

Q. For Tenaculum Forceps, it says, "All test articles complete 15 life cycles, resulting in validation of a" -- something -- "use count of 10"?

A. "Human use count of 10."

Q. Do you understand that to be saying that all of the Tenaculum Forcep articles passed 15 life cycles without failure?

A. Yes, I do.

Q. Do you have an understanding of why, for ProGrasp only, they would only need to meet 13 life cycles without failure while for Tenaculum they would need to meet 15 life cycles without failure?

A. Well, I don't know for certain, but it could -- number of test samples that were under test can influence the target number of uses that need to be satisfied to meet that rated use life target.

So I could see that the sample size is identified for ProGrasp. Clearly it says for ProGrasp Forceps and then it says "and Tenaculums."

So without knowing the details, I'm not sure, but that's one potential reason why the number of cycles that had to be completed is different.

Q. And but in each instance -- for ProGrasp, for example, it took 13 cycles to prove the 10-use target;

right?

A. Right.

Q. For Tenaculum, it took 15 cycles to prove the 10-use target; right?

A. If you don't mind, I'm reading this again.

(The witness reviewed the document.)

THE WITNESS: Yeah. I'm unclear on why the difference, but that's what the statement is -- is stating.

MR. VAN HOVEN: I'm going to load as Exhibit 269 tab 74.

(Deposition Exhibit 269 was marked for identification.)

MR. VAN HOVEN: This is Intuitive-00290826.

THE WITNESS: I have the hard copy.

BY MR. VAN HOVEN:

Q. That's all right. I'll put it on the screen also.

Can you take a look at this document. And I guess it's a five- or six-page document, but I guess look at it in some detail and let me know when you're ready to discuss it.

A. Okay.

(The witness reviewed the document.)

THE WITNESS: Okay. I've read it or reviewed